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| 09/927,049      | 08/09/2001  | Takeo Tanaami        | 010814              | 4111             |

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EXAMINER

BEISNER, WILLIAM H

| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/927,049

Applicant(s)

TANAAMI, TAKEO

Examiner

William H. Beisner

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004 and 07 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 March 2004 has been entered.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

Pages 4 and 5 of the instant specification refer to the claim number which is improper.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 30-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims include the following new matter:

a) Independent claims 30, 39 and 48 all include the new claim limitation “contains normally mobile biopolymer segments which are of known identities and of unknown identities”.

b) Independent claim 48 includes the new claim limitation “means for applying an electrical signal to said one or more electrodes to cause said known biopolymer segments to be immobilized at particular sites within said container, and to cause said mobile unknown biopolymer segments to approach said immobilized known biopolymer segments”.

c) New dependent claim 49 recites a the new claim limitation “means for optically viewing hybridized biopolymer segments”.

With respect to items (a)-(c) above, Applicant has not pointed out where the new (or amended) claim limitations are supported, nor does there appear to be a written description of the claim limitation limitations listed in items (a)-(c) above in the application as filed.

With respect to item (a) above, the instant application actually conveys to one of ordinary skill in the art that the known biopolymer segments are fixed, attached or immobilized to the container (See page 2, lines 1-2, 7-8; and page 6, lines 18-20). Nothing in the originally filed disclosure would lead one of ordinary skill in the art to conclude that applicants invention at the time of filing the application included limitations where known biopolymer segments are provided in a mobile state in the sample solution and immobilized to the “sites” using the electric field also used for hybridizing the unknown biopolymer segments.

With respect to item (b) above, for the same reasons as set forth to item (a) above, nothing in the originally filed disclosure would lead one of ordinary skill in the art to conclude that applicants invention at the time of filing the application included a means that is capable of

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causing known biopolymer segments provided in a mobile state in the sample solution to become immobilized to the "sites" using the electric field also used for hybridizing the unknown biopolymer segments.

With respect to item (c) above, while the instant specification discusses fluorescence, nothing in the originally filed disclosure would lead on of ordinary skill in the art to conclude that application's invention at the time of filing the application included a "means for optically viewing hybridized biopolymer segments".

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 48 and 49 rejected under 35 U.S.C. 103(a) as being unpatentable over Choong et al.(US 6,238,909) alone or further in view of Applicant's admission of prior art.

The reference of Choong et al. discloses a measuring device for hybridization of biopolymers. The device includes a container (10) that is separate and removable from the rest of the device. The device also includes electrodes (30) that are electrically insulated from the container. The reference also discloses that the device includes means for applying (4) an electrical signal to the electrodes to cause an unknown biopolymer segment to approach an immobilized (known) biopolymer to increase speed of hybridization and is capable of altering the direction of the electric field (See column 11, lines 54-63). In use, the device contains biopolymer segments that are both known and unknown. With respect to the claim limitations that the container is removable or movable relative to the rest of the device and/or electrodes, the reference of Choong et al. discloses that *"In some instances, it may be necessary to construct the device such that the electrodes are moveable, and are positioned with respect to the substrate after the substrate has been appropriately positioned (e.g., in three-dimensional structures, wherein the substrate is placed in the center of the structure, and the electrodes essentially surround the substrate in all directions). With a very large number of electrodes, e.g., ten or more, it is desirable that the configuration of the electrodes approximate that of a cylinder or sphere in either one- or three-dimensions, with the substrate being placed preferably at about the center. However, basically any arrangement of electrodes and substrate that could be employed in the invention to obtain electrostatic movement/bioconjugation of molecules are herein contemplated, and are within the knowledge and level of skill of one skilled in the art to achieve."* (See Column 9, lines 41-56). With respect to the claimed means for causing the known biopolymers to become immobilized to the sites within the container, in the absence of further positively recited structure, the primary reference inherently includes an immobilization

means, if not, the known biopolymers would not be attached to the substrate for performing the hybridization assay.

Claim 48 differs by reciting that the container is hermetically sealed.

While the reference of Choong et al. discloses that the container (10) can be a vessel or cuvette (See column 6, lines 10-17), the reference does not specifically recite that the vessel or cuvette is hermetically sealed. However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to hermetically seal the container during the testing process for the known and expected result of preventing contamination of the sample being processed.

Furthermore, page 2 of Applicant's specification discloses that positioning a DNA chip within a fluid holding cartridge is known in the art.

As a result, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to hermetically seal the container during the testing process for the known and expected result of preventing contamination of the sample being processed while providing a vessel for holding the fluid sample relative to the detection array on the test substrate surface.

With respect to claim 49, the reference discloses the use of a laser scanning system (See column 15, lines 59-64).

8. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wen-Tung et al.(US 2001/0005718) alone or further in view of Applicant's admission of prior art.

The reference of Wen-Tung et al. discloses a measuring device for hybridization of biopolymers. The device includes a container (5 or 1) that is separate and removable from the rest of the device. The device also includes electrodes (2 or 3) that are electrically insulated from the container. The reference also discloses that the device includes means for applying (4) an electrical signal to the electrodes to cause an unknown biopolymer segment to approach an immobilized (known) biopolymer to increase speed of hybridization and is capable of altering the direction of the electric field (See page 4, paragraph 0055). In use, the device contains biopolymer segments that are both known and unknown. With respect to the claim limitations that the container is removable or movable relative to the rest of the device and/or electrodes, the reference of Wen-Tung et al. discloses that *"According to the invention, the substrate is detachable and separated from the electrode. The substrate can be easily replaced after the completion of the hybridization reaction. Any suitable materials can be used to prepare the substrate. Preferably, the substrate is selected from silica, glass, a semiconductor, a nylon membrane, a nitrocellulose membrane or filter paper."* (See paragraph [0040]). With respect to the claimed means for causing the known biopolymers to become immobilized to the sites within the container, in the absence of further positively recited structure, the primary reference inherently includes an immobilization means, if not, the known biopolymers would not be attached to the substrate for performing the hybridization assay.

Claim 48 differs by reciting that the container is hermetically sealed.

While the reference of Wen-Tung et al. discloses that the container (1) can be a substrate with side walls (See Figure 2), the reference does not specifically recite that the container (1) is hermetically sealed. However, in the absence of a showing of criticality and/or unexpected



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results, it would have been obvious to one of ordinary skill in the art to hermetically seal the container during the testing process for the known and expected result of preventing contamination of the sample being processed.

Furthermore, page 2 of Applicant's specification discloses that positioning a DNA chip within a fluid holding cartridge is known in the art.

As a result, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to hermetically seal the container during the testing process for the known and expected result of preventing contamination of the sample being processed while providing a vessel for holding the fluid sample relative to the detection array on the test substrate surface.

***Allowable Subject Matter***

9. Claims 30-47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

The above claims would be allowable because the prior art of record fails to teach or fairly suggest a hybridization detection device that includes a container that is removable and separate from the electrodes wherein the electrodes are provided with protrusions formed at special positions corresponding to sites where the biopolymer segments gather within the container.

***Response to Arguments***

11. Applicant's arguments filed 01 March 2004 have been fully considered but they are not persuasive.

With respect to claim 48, Applicant argues that neither of the references of Choong et al. nor Wen-Tung et al. teach or suggest: a) a hermetically sealed container; b) a container that is removable replaceably; c) a means for causing said known biopolymer to be immobilized at particular sites within the container; and d) means for optically viewing the hybridized segments.

In response to item a) above, the Examiner is of the position that the prior art and the level of skill in the art teaches and/or suggests to one of ordinary skill in the art to hermetically seal the container.

In response to item b) above, as stressed in the prior art rejections above over either of the references of Choong et al. or Wen-Tung et al., both of these references disclose that the containers are independent of the electrodes and are movable with respect to the electrodes. Whether or not the intention of the disclosures of the patent references was for interchangeability, the references are structurally the same as that of the structure instantly claimed.

In response to item c) above, both the references of Choong et al. and Wen-Tung et al. have known biopolymer segments immobilized to sites within the containers and in the absence of further positively recited structure, meets in the instant claim language.


In response to item d) above, the reference of Choong et al. discloses the use of a means for optically viewing the hybridized segments.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB